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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,608	12/02/2003	Kenneth A. Martin	1190.14	4967

29637 7590 09/21/2006

BUSKOP LAW GROUP, P.C.
1776 YORKTOWN
SUITE 550
HOUSTON, TX 77056

EXAMINER	
KIM, TAEYOON	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,608	MARTIN ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *8-10 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21 are pending.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-20) in the reply filed on Aug. 7, 2006 is acknowledged.

In addition, applicant's election of the following species in the reply filed on Aug. 28, 2006 is acknowledged.

The elected species are:

Group 1: Vitamin B
Group 2: soy protein
Group 3: flax seed
Group 4: psyllium
Group 5: magnesium
Group 6: protease
Group 7: calcium gluconate

Claim 21 is withdrawn from consideration as being drawn to non-elected subject matter. Claims 8-10 are withdrawn from consideration as being drawn to non-elected species. Claims 1-7 and 11-20 have been considered on the merits.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/241,542 (U.S. Patent 6,660,308 B1), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Claim 1 and its dependents contain subject matters such as "cetyl myristoleate" and "s-adenosylmethionine", which are not supported by the earlier filed application.

Therefore, the benefit of a prior-filed application under 35 U.S.C. 120 is not granted.

Claim Objections

Claims 1-7 and 11-20 are objected to because of the following informalities: There are typos in claim 1 and its dependent. Claim 1 appears to start with "an" instead of "a". The term "muskuloskeletal" in claim 1 and its dependents appears to be "musculoskeletal". Appropriate correction is required.

Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 14 is dependent on claim 13, which claims a digestive enzyme. A protease is the limitation to the digestive enzyme in claim 14. Since a protease is a broader subject matter than a digestive enzyme, claim 14 does not further limit the subject matter of claim 13.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 11-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 and its dependents, the terms "acetyl myristoleate" are claimed. Throughout the application, "acetyl" as well as "cetyl" have been used for myristoleate. It is not clear whether applicant points out the subject matter as "acetyl myristoleate" or "cetyl myristoleate". For the examination purpose, it has been interpreted as "cetyl myristoleate".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 11, 12 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heisey et al. (US 2002/0132780 A1) in view of Stone (supra).

Claims 1-7, 11, 12 and 15-20 are drawn to an ingestible supplement for treating musculoskeletal disorders comprising (a) about 250 mg - 2500 mg of 2-amino-2-deoxyglucose sulfate, 2-amino-2-deoxyglucose sulfate hydrochloride, n-acetyl 2-amino-2-deoxyglucose sulfate, or combinations thereof; (b) about 40 mg - 750 mg of cetyl myristoleate; (c) about 40 mg - 800 mg of s-adenosylmethionine; (d) about 200 mg - 2000 mg of a protein; (e) 100 mg to 2500 mg of Vitamin B and (f) about 1000 mg - 9000 mg of a fiber (claim 1); a limitation of the amount of (a) being about 1000 mg – 2000 mg (claim 2); a limitation of the amount of (a) being about 1200 mg – 1500 mg (claim 3); a limitation to a protein of (d) being soy protein (claim 4); a limitation to the supplement being further comprising about 0.1 mg-20 mg of fatty acid (claim 5); a limitation of the fatty acid being derived from flax seed (claim 6); a limitation of vitamin B being selected from vitamin B1, B3, B5, B6, B-12 or combination thereof (claim 7); a limitation to the fiber being a psyllium (claim 11); a limitation to the supplement being further comprising about 1 to 20 mg of magnesium (claim 12); a limitation to the supplement being further comprising about 250 to 1500 mg of calcium gluconate (claim 15); a limitation to the supplement being further comprising about 250 to 1500 mg of vitamin A (claim 16); a limitation to the vitamin A being beta carotene (claim 17); a limitation to the vitamin A being derived from fish oil (claim 18); a limitation to the supplement being further comprising about 10 to 500 mg of bioflavonoids from the group of quercetin, grape seed

extract and combinations thereof (claim 19); a limitation to the supplement being further comprising about 250-1000 mg of chondroitin (claim 20).

Heisey et al. teach the composition comprising glucosamine, SAMe, vitamins (A being beta carotene, B and C), psyllium, omega-3 fatty acid, soy protein, magnesium, calcium gluconate, flavanols (bioflavonoids) and chondroitin (see paragraphs 9, 71, 77, 78, 86, 102, 108, 118-123, 124-127, 136, 138-143, 146 and 148).

Heisey et al. also teach the amount of glucosamine being 250-1900 mg, SAMe being 200-400 mg, chondroitin being 250-800 mg, about 100 mg of vitamins (5% of total less than 18-19 grams of composition).

Heisey et al. do not particularly teach the use of cetyl myristoleate in the composition.

Ehrenpreis et al. teach the use cetyl myristoleate at about 100-800 mg for rheumatoid arthritis (an inflammatory musculoskeletal disorder) (see paragraph 26 and Table 7).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to combine cetyl myristoleate of Ehrenpreis et al. with the composition of Heisey et al.

M.P.E.P. §2144.06 states "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted)

(Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also *In re* Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte* Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

Since cetyl myristoleate of Ehrenpreis et al. is used for the treatment of musculoskeletal disorder, this ingredient can be used along with the composition of Heisey et al. for the same purpose of treating musculoskeletal disorders.

Although Heisey et al. in view of Ehrenpreis et al. do not particularly teach flavanols (bioflavonoids) being from quercetin or grape seed extract, these are well known in the art as a flavanol as supported by Murray, M. T. (Quercetin: nature's antihistamine – Dr. Murray's Natural Healing, 1998 http://www.findarticles.com/p/articles/mi_m0FKA/is_n4_v60/ai_20471626/print).

Heisey et al. in view of Ehrenpreis et al. do not particularly teach vitamin A being derived from fish oil. However, it is well known in the art that fish oil is a source of vitamin A supported by Cod liver oil, fish oil and Omega 3 (2002, http://www.healingdaily.com/detoxification-diet/cod-liver-oil.htm).

Heisey et al. in view of Ehrenpreis et al. do not particularly teach flax seed as an ingredient. However, since omega-3 fatty acid can be obtained from flax seed as

supported by Cod liver oil, fish oil and Omega 3 (supra), flax seed can be added as a same purpose of omega-3 fatty acid. See *In re* Scott, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963); Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980), 209 USPQ at 759. See also M.P.E.P. §2144.06.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claims 1-5, 7, 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 2003/0124200) in view of Ehrenpreis et al. (US 2004/0241256).

Claims 1-5, 7, 11 and 20 are drawn to an ingestible supplement for treating musculoskeletal disorders comprising (a) about 250 mg - 2500 mg of 2-amino-2-deoxyglucose sulfate, 2-amino-2-deoxyglucose sulfate hydrochloride, n-acetyl 2-amino-2-deoxyglucose sulfate, or combinations thereof; (b) about 40 mg - 750 mg of cetyl myristoleate; (c) about 40 mg - 800 mg of s-adenosylmethionine; (d) about 200 mg - 2000 mg of a protein; (e) 100 mg to 2500 mg of Vitamin B and (f) about 1000 mg - 9000 mg of a fiber (claim 1); a limitation of the amount of (a) being about 1000 mg – 2000 mg (claim 2); a limitation of the amount of (a) being about 1200 mg – 1500 mg (claim 3); a limitation to a protein of (d) being soy protein (claim 4); a limitation to the supplement being further comprising about 0.1 mg-20 mg of fatty acid (claim 5); a limitation of vitamin B being selected from vitamin B1, B3, B5, B6, B-12 or combination thereof

(claim 7); a limitation to the fiber being a psyllium (claim 11); a limitation to the supplement being further comprising about 250-1000 mg of chondroitin (claim 20).

Stone teaches a food supplements comprising glucosamine sulfate (2-amino-2-deoxyglucose sulfate) or glucosamine hydrochloride (2-amino-2-deoxyglucose sulfate hydrochloride), cetyl myristoleate, S-adenosylmethionine, chondroitin sulfate (claim 20), soy lecithin (soy protein; claim 4), vitamins, mineral, and fatty acid for cartilage enhancement (See paragraphs 23, 32, 39, 50).

Stone does not particularly teach vitamins being vitamin B and its species (B1, B3, B5, B6, B-12).

Ehrenpreis et al. teach the use of B-vitamin (including B1, B3, B5, B6, B-12) in a food supplement containing glucosamine, cetyl myristoleate, and S-adenylmethionine for rheumatoid arthritis (an inflammatory musculoskeletal disorder) (see paragraph 26).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use B-vitamin of Ehrenpreis et al. in the ingestible supplement of Stone.

The skilled artisan would have been motivated to make such a modification because vitamin B along with other vitamins are commonly added to a food supplement to improve and/or treat musculoskeletal disorders.

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.

Stone does not particularly teach the range of amount of each ingredient of the supplement.

Ehrenpreis et al. teach the amount of glucosamine being 1000-1500 mg (Table 5), chondroitin sulfate being 100-1000 mg, cetyl myristoleate being 100-800 mg (Table 8).

Furthermore, the selection of specific amount of the ingredients of the supplement of the claimed invention would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that determination of optimal amount of each ingredient to add in order to best achieve the desired results. A holding of obviousness over the cited claims is therefore clearly required. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382.; See also M.P.E.P. § 2144.05.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (supra) in view of Ehrenpreis et al. (supra), in further view of Collin (US 6,428,817; issued on Aug. 6, 2002).

Claim 6 is drawn to a limitation of the fatty acid being derived from flax seed.

Stone in view of Ehrenpreis et al. teache a food supplements comprising glucosamine sulfate (2-amino-2-deoxyglucose sulfate) or glucosamine hydrochloride (2-

amino-2-deoxyglucose sulfate hydrochloride), cetyl myristoleate, S-adenosylmethionine, chondroitin sulfate (claim 20), soy lecithin (soy protein; claim 4), vitamins, mineral, and fatty acid for cartilage enhancement (See paragraphs 23, 32, 39, 50) and their amount in the composition (see above).

Stone in view of Ehrenpreis et al. do not teach that fatty acid in the supplement being from flax seed.

Collin teaches flax seed for the composition to treat arthritic problems in animals (see Example 1).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to combine flax seed of Collin with the ingredient of Stone in view of Ehrenpreis et al.

The skilled artisan would have been motivated to make such a modification because since the use of flax seed in the composition of Collin is for treating arthritis which is the same purpose as the composition of Stone, flax seed of Collin can be combined with other ingredient of Stone's composition to obtain a third composition for the very same purpose.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (supra) in view of Levin (US 6,677,321; filed on Nov. 28, 2000).

Claims 13 and 14 are drawn to a limitation to the supplement being further comprising about 1 to 20 mg of digestive enzyme (claim 13); a limitation to the digestive enzyme being protease (claim 14).

Stone teaches a food supplements comprising glucosamine sulfate (2-amino-2-deoxyglucose sulfate) or glucosamine hydrochloride (2-amino-2-deoxyglucose sulfate hydrochloride), cetyl myristoleate, S-adenosylmethionine, chondroitin sulfate (claim 20), soy lecithin (soy protein; claim 4), vitamins, mineral, and fatty acid for cartilage enhancement (See paragraphs 23, 32, 39, 50).

Stone does not particularly teach a digestive enzyme or protease being further supplemented to the composition.

Levin teaches the use of a protease in a composition for treatment of inflammatory disease.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use a protease taught by Levin in the composition of Stone.

The skilled artisan would have been motivated to make such a modification because since the composition of Levin comprising a protease is used for the same purpose as the composition of Stone, a protease of Levin can be combined with other ingredient of Stone's composition to obtain third composition for the same purpose.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim
Patent Examiner
Art Unit 1651

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651